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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,075	05/10/2000	GARY L. JOHNSON	CPI-042CPUS	6811

7590 11/03/2003

GIULIO A DECONTI JR
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/403,075

Applicant(s)
Johnson

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 11, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 12, 19, 20, 43, 50, 52-54, 58-61, and 68-71 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70 is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 19, 20, 43, 50, 52-54, 58-61, 68, 69, and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. The Amendment filed September 11, 2003 (Paper No. 15) in response to the Office Action of March 11, 2003 (Paper No. 12) is acknowledged and has been entered. Previously pending claims 1-4, 19-20, 52, 58-59, 68-71 have been amended. Claims 1-4, 12, 19-20, 43, 50, 52-54, 58-61, 68-71 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are maintained:

Claim Rejections - 35 USC § 112

4. Claims 2-4, 19-20, 43, 52-54, 58-61, 68, 69 and 71 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 12, Section 4, pages 1-2.

Applicant argues that (a) the specification teaches MEKK molecules other than SEQ ID Nos 3 and 4 and that making variants is a standard technique to the ordinary skilled artisan, (b) enablement is not precluded by the necessity of experimentation.

The arguments have been considered but have not been found persuasive because (a') although the specification teaches other MEKK molecules, the specification does not teach how to use the broad range of sequences claimed with the set that are 95% identical to the sequences set forth as SEQ ID NO:3 and 4. Further, the specification does not teach how to make sequences with 95% identity to SEQ ID NO:3 or 95% identity to SEQ ID NO:4 that would function as claimed in order to, for example, mediate apoptosis, phosphorylate an MKK protein. Although

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the specification proposes methods of isolating the claimed molecules and screening for the claimed functions, this does not satisfy the “method of making” requirement of 35 USC 112, first paragraph as the specification does not teach how to actually make the claimed invention. Although the specification teaches that MEKK homologs can be generated by the present combinatorial approach by the manipulation of certain domains or mutagenesis (p. 15), the specification does not teach which 5% of the 5253 residues of SEQ ID NO:3 or which of the 1490 residues of SEQ ID NO:4, in the cited domains or in the conserved sequences, can be altered and still retain the contemplated and claimed functions of the instant invention, (b’) given that the claims encompass the alteration of 263 nucleic acid residues as well as 75 amino acid residues, in the absence of further guidance in the specification, the skilled artisan is left with random experimentation in order to make the claimed invention because it is noted that by factorial analysis the number of possible combinations of alterations, even for the encoded polypeptide, is more than the number of stars in the universe. The arguments have been considered but have not been found persuasive and the rejection is maintained.

5. Claims 1-4, 12, 19-20 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 12, Section 6, pages 2-4.

Applicant argues that claim 1 as amended is drawn to “a full complement of SEQ ID NO:3” which Examiner has indicated to be fully enabling, thus Examiner is requested to withdrawn the rejection. The argument has been considered but has not been found persuasive because “a” full complement is broadly read to include not only the full complement, but also is read to include species that are fully

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complementary to a portion of SEQ ID NO:3. It is noted that Examiner did not state that "a full complement of SEQ ID NO:3" was enabled but rather stated that "a polynucleotide completely complementary to the full length of SEQ ID NO:3" is enabled. Amendment of claim 1 to substitute "the" for the term "a" would obviate this rejection for claims 1-4 and 12.

As drawn to claims 19-20, Applicant further argues that one would recognize that a probe that selectively hybridizes to SEQ ID NO:3 does not include primers and probes that bind other nucleic acid molecules or to other members of the MEKK family members. The argument has been considered but has not been found persuasive because the specification does not define the phrase "selectively hybridizes". Further, the specification does not teach any method of a probe selectively hybridizing only to SEQ ID NO:3 or any other molecule. On page 12 the specification discusses hybridization wherein it is stated that hybridization is used to "identify similar nucleic acid molecules". Further, the specification then recites, explicit stringent hybridization condition (see lines 27-30). In the absence of specific stringent hybridization conditions, the claims read on the full range of hybridization conditions from very low to very high wherein the probe would bind specifically, that is to a few or to all of the nucleic acid residues, to a whole universe of polynucleotides. Given the claims as currently constituted, for the reasons previously set forth, the claims read on detection of polynucleotides that have neither structural nor functional properties of SEQ ID NO:3 and which encode polypeptides with neither structural nor functional. properties of SEQ ID NO:4. The

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arguments have been considered but have not been found persuasive and the rejection is maintained.

In light of Applicant's arguments wherein it appears that Applicant intended to claim a method of detecting only SEQ ID NO:3, Applicant might consider amending claim 19 to recite the highly stringent conditions disclosed on page 13 of the specification and to further amend the claim to recite a nucleic acid probe or primer consisting of a sequence of SEQ ID NO:3 which encodes a sequence of SEQ ID NO:4 if support for such an amendment could be found in the specification.

6. Claims 43 and the claims dependent upon claim 43 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 12, Section 8, page 5.

Applicant argues that support for the claimed amendment is found on page 6, lines 31-34. The argument has been considered but has not been found persuasive because the claim as written is drawn to an isolated nucleic acid molecule that **includes** a fragment having 95% identity to residues 875-1493. It is clear that the limitation "where % identity is determined over the entire length of residues 875-1493" is meant to clarify that this variation is only in the part of the claimed molecule that includes said fragment. The cited support is drawn only to isolated fragments. The cited support is not commensurate in scope with the claims as currently constituted. The arguments have been considered but have not been found persuasive and the rejection is maintained. Amendment of claim 43 to recite, for example, "an isolated nucleic acid that consists of an isolated nucleic acid molecule which encodes" would obviate the rejection.

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7. Claims 52-54 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 12, Section 10, pages 5-6.

Applicant argues that Examiner has misread the instant claims and that the claims are directed to a nucleic acid molecule that encodes a polypeptide in which one of the amino acid residues that is equivalent to the amino acid residue present at positions 871-874 of SEQ ID NO:4 is substituted with another amino acid and a skilled artisan would understand that the instant claim is directed to nucleic acid molecule that encode a polypeptide with a mutated residue in one or more of the positions equivalent to positions 871-874. The argument has been considered but has not been found persuasive because neither the claim nor the specification defines what “an amino acid equivalent” is. Further, how would one skilled in the art determine what positions are equivalent to positions 871-874. The arguments have considered but have not been found persuasive and the rejection is maintained.

8. Claims 1, 2, 4, 12 19, 20, 43, 50, 58 and 60 remain rejected under 35 USC 102(b) for the reasons previously set forth in Paper No. 12, Section 13, pages 7-9.

Applicant argues that examiner has misinterpreted the pending claims as being directed to a complement of some portion of the full length sequence disclosed. Applicants claims are directed to nucleic acid molecules that are complementary to the full length of SEQ ID NO:3 or the full length of the nucleic acid molecules that encodes SEQ ID NO:4. Since WO94/242259 discloses a fragment of SEQ. ID NO:3 that is only 61.7% of the length of SEQ ID NO:3, the prior art reference does not anticipate the claimed invention. The argument has been considered but has not been found persuasive because the claims are not

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drawn to full length completely complementary sequences for the reasons set forth above. Further, the prior art reference teaches an isolated nucleic acid molecule which comprises a polynucleotide sequence with 100% identity to residues 693-2501 of SEQ ID NO:3 which region is a full complement of SEQ ID NO:3. All of the limitations of the claims are met for the reasons of record. The arguments have been considered but have not been found persuasive and the rejection is maintained.

9. Claims 1 and 20 remain rejected under 35 USC 102(b) for the reasons previously set forth in Paper No. 12, Section 14, page 9.

Applicant argues that the invention is directed to compliments of the full length MEKK1 molecules disclosed in the specification. The prior art primers cannot anticipate the claimed invention because they are too small. The argument has been considered but has not been found persuasive because the claims are not drawn to full length completely complementary sequences. The prior art primers meet the limitations of the claims as currently constituted. The arguments have been considered but have not been found persuasive and the rejection is maintained.

10. Claims 1 and 3 remain rejected under 35 USC 102(b) for the reasons previously set forth in Paper No. 12, Section 16, pages 10-11.

Applicant argues that because WO 92/24159 is deficient and US Patent No. 5,968781 does not make up for the deficiencies, that the rejection should be withdrawn. The argument has been considered but has not been found persuasive because, for the reasons set forth above, WO 92/24159 is not deficient. Further, Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are

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relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The arguments have been considered but have not been found persuasive and the rejection is maintained.

11. Claim 70 appears to be free of the art and allowable.

12. All other objections and rejections recited in Paper No. 12 are hereby withdrawn.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.


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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
October 29, 2003